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EXAMINER	
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ART UNIT	PAPER NUMBER
1647	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/579,744	ONICHTCHOUK, DARIA	
	Examiner	Art Unit	
	IAN DANG	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *3-8,11-13,22-40,42 and 43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,9,10,14-21 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/18/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group VI, claims 1, 2, 9, 10, 14-21, and 41 in the reply filed on 09/24/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Claims 3-8, 11-13, 22-40, and 42-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1, 2, 9, 10, 14-21, and 41 are under examination.

The Examiner requests clarification regarding the status of claim 2. Please note that the response to the restriction requirement filed 09/24/2008 indicates that claim 2 is part of the claims of group VI to be examined. However, the claim set filed 09/24/2008 indicates that claim 2 is withdrawn. These conflicting statements render the status of claim 2 indefinite. For the purpose of the examination of the claims in this office action, the Examiner has decided to include claim 2.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

On pages 36-39 of the specification, the description of the drawings for all Figures, which have various parts, need to be identified as such in the brief description (ex. "Figures 1A-B…").

Claim Objections

Claims 16 and 41 are objected to because of the following informalities:

Claim 16 is objected to because the recitation of "pancreatic cells more particularly beta cells or exocrine cells" renders the claims unclear. The recitation of " beta cells and exocrine cells" in a separate dependent claim would clarify the meaning of the claim. For instance, the dependent claim reciting "the composition of claim 16 wherein the cells are beta cells or exocrine cells" would be would overcome the rejection.

In addition, claim 16 is rejected because the term "particularly" adds confusion to the claim, since it is unclear if Applicants prefer to have cells over tissue. The Examiner suggests that the removal of the phrase "particularly pancreatic cells" from the claim would overcome the objection.

Claim 41 is objected to because it recites "Kit comprising at least one." The recitation of "*A* kit...of *an* amino acid…" would overcome the objection.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 9, 10, 14-21, and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 9, 10, 14-21, and 41 are indefinite because the elements recited in the claim do not constitute proper Markush groups. The claims are indefinite in the alternative use of "and/or" because it is

not clear what controls which of these limitations. (See especially claims 1, 2, and 20.) See MPEP § 2173.05(h).

Claim 1 is indefinite because the recitation of SF6 protein and functional fragment thereof" is indefinite. The specification does not provide any definition for the claimed SF6 protein. It is not clear as to what is encompassed by the phrase "SF6 protein and functional fragment thereof." For instance, it may encompass any homologs, orthologs, fragments, variants, and fragments, and many other proteins related to the SF6 protein

Claim 1 is indefinite because it uses an acronym without first defining what they represent in the independent claims (see for example, "SF6"). While the claims can reference acronyms, the material presented by the acronym must be clearly set forth at the first use of the acronym.

Claim 41 is indefinite because the recitation of the phrase "amino acid molecule" is indefinite. The recitation of the term "molecule" is unclear as to what the term "molecule" refers to. The recitation of protein or polypeptide would overcome the rejection.

Regarding claim 14, the phrase "e.g." renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 112, First paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 9, 10, 14-21, and 41 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The sequences for SF6 protein are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The specification does not provide the sequences in the

sequence listing for the SF6 protein of the claimed invention. Instead Applicants only provided the accession numbers for the SF6 protein in table 2 on page 41 in the specification. These accession numbers are not appropriate because the sequences of these accession numbers are regularly updated to include modifications to the sequences of record.

Claims 1, 2, 9, 10, 14-21, and 41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The deposit of the biological material is considered necessary for the enablement of the current invention (see MPEP Chapter 2400 and 37 C.F.R. §§ 1.801-1.809). Elements required for practicing a claimed invention must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If a deposit (biological materials disclosed at Table 2 on page 41 of the specification) is made under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g. see 961 OG 21, 1977), and Applicants, their assignee or their agent needs to provide a declaration containing the following:

1. the current address of the ATCC.
2. a declaration, or statement over attorney's signature stating that all restrictions imposed by the depositor on the availability to the public of the deposited biological material be irrevocably removed upon the granting of the patent (see MPEP Chapter 2410.01 and 37 C.F.R. § 1.808).
3. A deposit made before or during pendency of an application for patent shall be made for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposit was received by the depository.

Claim Rejections - 35 USC § 101/112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" – A utility that is specific to the subject matter claimed. This contrasts with a general utility that would be applicable to the broad class of the invention.

"Substantial" – A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" – Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the Applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

See also the MPEP at § 2107-2107.02.

Claims 1, 2, 9, 10, 14-21, and 41 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible utility or, in the alternative asserted utility or a well established utility.

The claims are drawn to pharmaceutical composition comprising SF6 protein and/or functional fragment thereof.

The specification discloses the following facts regarding the claimed SF6 protein:

- At page 6 the specification teaches that SF6 is a secreted glycoprotein expressed in CNS, PNS, and subsets of mesenchymal cells (Nelson B.R. et al., (2002) Gene Expr Patterns. 2: 7-15) and that SF6 contains a calcium ion binding domain (lines 25-27).
- At pages 36-37, the specification provides examples for the expression of the SF6 protein. Figure 6 shows the analysis of SF6 expression in mammalian (mouse) tissues. Figure 6A shows the real-time PCR analysis of SF6 expression in wild type mouse tissues (referred to as

wt-mice) and in tissues of mice fed with a control diet (referred to as control diet). Figure 6B shows the real-time PCR analysis of SF6 expression in tissues of mice fed with a control diet (without brain). Figure 6C shows the real-time PCR analysis of SF6 expression in genetically obese mice (referred to as ob/ob-mice) compared to wild type mice, and in mice fed with a high fat diet (referred to as HFD-mice) compared to mice fed with a control diet (page 36 line 31 to page 37 line 4).

- At page 41, the specification teaches that the SF6 is identified as the Mus musculus protein with the Genbank accession number NP_058023 and as the Homo sapiens protein with the Genbank accession number NP_006150 (Table 2).
- At page 47, the specification teaches that the high expression level of SF6 in the hypothalamus and brain as well as the regulation of gene expression in mouse models for the metabolic syndrome as described above suggests that it might play a role in the regulation of energy homeostasis (lines 33-36).

However, the instant specification does not teach any specific functional characteristics of the SF6 protein. Although the specification discloses that the SF6 protein may be involved in energy homeostasis based on the expression level of SF6 mRNA in the brain, the specification does not provide any information regarding SF6 protein in the context of a cell or organism or any methods or working examples that indicate that the polypeptides of the instant invention is involved in any activities or diseases states. The real-time PCR analysis of SF6 expression does not provide sufficient evidence regarding the specific functional characteristics of the SF6 protein. Since significant further research would be required of the skilled artisan to determine how the SF6 protein is involved in any activity, the asserted utilities are not substantial. Since the utility is not presented in mature form and significant further research is required, the utility is not substantial. The specification asserts the following as

patentable utilities for the claimed SF6 protein in a pharmaceutical composition:

1) to screen libraries of compounds for drug discovery (page 30, lines 11 to page 33 line 36)

2) to provide antibodies which specifically bind to the proteins may be used for the diagnosis of conditions or diseases characterized by or associated with over- or under-expression of the proteins of the invention (page 26, liens 11-21)

3) to provide a method of diagnosis of a disease associated with SF6 protein (page 28, line 8 to page 29 line 8)

Each of these shall be addressed in turn.

1) to screen library of compounds for drug discovery. This asserted utility is not specific or substantial. Such assays can be performed with any polypeptide or polynucleotide. Nothing is disclosed about how the SF6 protein is affected by the compounds. Additionally, the specification discloses nothing specific or substantial for the molecular targets that can be identified/selected/validated by this method. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

2) to provide antibodies which specifically bind to the proteins may be used for the diagnosis of conditions or diseases characterized by or associated with over- or under-expression of the proteins of the invention. This asserted utility is not specific or substantial. Such diagnostic can be performed with any polypeptide. Although the specification discloses that SF6 might play a role in the regulation of energy homeostasis (lines 33-36), the specification also discloses nothing about antibodies binding to SF6 or how antibodies can be used to diagnose a condition associated with SF6 protein. In addition, the specification does not disclose any disorders associated with the SF6 protein. Significant further experimentation would be required of the skilled artisan to identify individuals with such a disease. Since

this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

3) to provide a method of diagnosis of a disease associated with SF6 protein. This asserted utility is not specific or substantial. The disclosed method of treatment can be performed with any polypeptides. Further, the specification does not disclose a specific disease or condition that can be treated with the SF6 protein or a disease associated with the SF6 protein. Significant further experimentation would be required of the skilled artisan to identify individuals with such a disease. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

The presence of the calcium ion binding domain cannot be reliably used to predict the function of the protein named SF6. In addition, the example of Figure 6 teaching that the analysis of SF6 expression in mammalian (mouse) tissues and disclosing that the high expression level of SF6 in the hypothalamus and brain as well as the regulation of gene expression in mouse models for the metabolic syndrome as described above suggests that it might play a role in the regulation of energy homeostasis do not provide support for any specific function. From the specification these teachings in the specification are mere suggestions for experimental investigation to determine what activities the SF6 protein might have and what practical use may be derived from such activities.

Therefore, the information regarding SF6 protein in the specification does not establish the claimed protein has a credible, specific, and substantial utility

Claims 1, 2, 9, 10, 14-21, and 41 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, credible utility,

asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112, First paragraph (Written Description)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 9, 10, 14-21, and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

1. Claims 1, 2, 9, 10, 14-21, and 41 are drawn to a pharmaceutical composition of SF6 protein.

Although Applicant discloses that SF6 protein is a secreted glycoprotein expressed in CNS, PNS, and subsets of mesenchymal cells (page 6, lines 24-27), Applicant has not provided any information regarding the identifying structural characteristics of functional fragment of the SF6 protein and the biological function of the SF6 protein that is used in the pharmaceutical composition. The specification and the claim fail to disclose any structural identifying characteristics of the functional fragment of the SF6 protein and the biological activity of the SF6 protein in the claimed pharmaceutical composition.

Therefore, Applicant has not satisfied the requirement for written description because the claimed functional fragment of the SF6 protein of claim 1 encompass a genus of SF6 protein, which includes variants, mutants, and derivatives whose identifying characteristic are not described. The specification provides 2 accession numbers as examples for the SF6 protein (Accession number NP_058023 for Mus musculus and accession number NP_006150 for homo sapiens, page 41, Table 2), but it does not provide

any description of the special features for the claimed SF6 protein and functional fragment that is used in the pharmaceutical composition. Furthermore, the specification does not provide any teachings sufficient to one of skill in the art to identify the numerous SF6 protein and functional fragments encompassed by the claims. Thus, Applicants have not provided any identifying structural characteristics or properties of the instant SF6 protein and biological function of the SF6 protein, such that one of skill would be able to predictably identify the encompassed SF6 protein and function fragment of the instant claims.

Based on Applicants' disclosure and knowledge within the art, those of skill in the art would conclude that Applicants would not have been in possession of the claimed genus of SF6 protein and functional fragment based on the disclosure of the mouse and human full length SF6 protein. Thus, applicant was not in possession of the claimed genus and the written description requirement is not satisfied.

2. Claims 14 is drawn to a pharmaceutical composition of SF6 protein for the manufacture of an agent for detecting and/or verifying, for the treatment, alleviation and/or prevention of pancreatic diseases (e.g. diabetes such as insulin dependent diabetes mellitus, non insulin dependent diabetes mellitus or latent autoimmune diabetes in adults), obesity, metabolic syndrome and/or other metabolic diseases or dysfunctions.

Although Applicant discloses functional characteristics of the agent in claim 14, Applicant has not provided any information regarding the identifying structural characteristics of the agent that can be used for detecting and/or verifying, for the treatment, alleviation and/or prevention of pancreatic diseases, obesity, metabolic syndrome and/or other metabolic diseases or dysfunctions. The specification teaches that the term "agent" as used herein describes any molecule, e.g. protein or pharmaceutical, with the capability of altering or mimicking the physiological function of one or more of the proteins of the invention (page 31, lines 21-23) and that candidate agents are also found among biomolecules including peptides, saccharrides, fatty acids, steroids, purines, pyrimidines, nucleic acids and derivatives, structural

analogs or combinations thereof (page 31, lines 34-36), but the claim fail to disclose any structural identifying characteristics of the agent that can be used for detecting and/or verifying, for the treatment, alleviation and/or prevention of pancreatic diseases, obesity, metabolic syndrome and/or other metabolic diseases or dysfunctions.

Therefore, Applicant has not satisfied the requirement for written description because the claimed agent in claim 14 encompass a genus of agent whose identifying structural characteristic are not described. The specification does not provide any examples for the claimed agent and does not provide any description of the special features for the claimed agent that can be used for detecting and/or verifying, for the treatment, alleviation and/or prevention of pancreatic diseases, obesity, metabolic syndrome and/or other metabolic diseases or dysfunctions. Furthermore, the specification does not provide any teachings sufficient to one of skill in the art to identify the numerous agents encompassed by the claims. Thus, Applicants have not provided any identifying structural characteristics or properties of the instant agent, such that one of skill would be able to predictably identify the encompassed agent of the instant claims.

Based on Applicants' disclosure and knowledge within the art, those of skill in the art would conclude that Applicants would not have been in possession of the claimed genus of agent. Thus, applicant was not in possession of the claimed genus and the written description requirement is not satisfied.

3. Claims 14 is drawn to a pharmaceutical composition of SF6 protein for the manufacture of an agent for detecting and/or verifying, for the treatment, alleviation and/or prevention of pancreatic diseases (e.g. diabetes such as insulin dependent diabetes mellitus, non insulin dependent diabetes mellitus or latent autoimmune diabetes in adults), obesity, metabolic syndrome and/or other metabolic diseases or dysfunctions. Although Applicant discloses that metabolic syndrome and/or other metabolic diseases or

dysfunctions is obesity or pancreatic disease, Applicant has not provided any information regarding the identifying characteristics of the metabolic syndrome and/or other metabolic diseases or dysfunctions that can be used for detecting and/or verifying, for the treatment, alleviation and/or prevention of numerous metabolic syndromes and/or other metabolic diseases or dysfunctions with an agent. The specification and the claim fail to disclose any identifying characteristics of the metabolic syndrome and/or other metabolic diseases or dysfunctions that can be used for detecting and/or verifying, for the treatment, alleviation and/or prevention of metabolic syndromes and/or other metabolic diseases or dysfunctions with an agent.

Therefore, Applicant has not satisfied the requirement for written description because the claimed metabolic syndrome and/or other metabolic diseases or dysfunctions disclosed in claim 14 encompasses a genus of diseases whose identifying characteristics are not described. The specification provides obesity and pancreatic diseases as examples for metabolic syndrome and/or other metabolic diseases or dysfunctions, but it does not provide any description of the special features for the claimed metabolic syndrome and/or other metabolic diseases or dysfunctions that can be used for detecting and/or verifying, for the treatment, alleviation and/or prevention with an agent. Furthermore, the specification does not provide any teachings sufficient to one of skill in the art to identify the numerous metabolic syndromes and/or other metabolic diseases or dysfunctions encompassed by the claims. Thus, Applicants have not provided any identifying characteristics or properties of the instant metabolic syndrome and/or other metabolic diseases or dysfunctions such that one of skill would be able to predictably identify the encompassed metabolic syndrome and/or other metabolic diseases or dysfunctions of the instant claims.

Based on Applicants' disclosure and knowledge within the art, those of skill in the art would conclude that Applicants would not have been in possession of the claimed genus of metabolic syndrome and/or other metabolic diseases or dysfunctions based on the disclosure of the species of pancreatic diseases and obesity relevant identifying characteristics. Thus, applicant was not in possession of the claimed genus and the written description requirement is not satisfied.

Claim Rejections - 35 USC § 112 (Enablement)

Furthermore, even if claims 1, 2, 9, 10, 14-21, and 41 possessed utility under 35 USC 101, they would still be rejected under 35 USC 112, first paragraph, because the specification, while being enabling for a pharmaceutical composition and a kit comprising the SF6 protein that is the full length polypeptide with the genbank accession NP_006150, does not reasonably provide enablement for a pharmaceutical composition and a kit comprising SF6 protein and/or function fragment thereof from any and all species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include: (1) Nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the breath of the claims, (7) the quantity of experimentation needed, (8) relative skill of those in the art.

Nature of the invention and breath of the claims

The claimed invention is drawn to a pharmaceutical composition comprising a SF6 protein and/or functional fragment thereof and is drawn to a kit comprising at least one of a SF6 protein. The invention is excessively broad because the recitation of claims 1 and 41 encompass a large number of fragments, derivatives, and variants for the SF6 protein. The recitation of the words "fragment" and "isoform" are interpreted to include fragments of SF6 protein that can be as few as one amino. The recitation of claim 1 and claim 41 includes a large number of SF6 protein. Moreover, the SF6 protein can also include proteins from any and all species. In table 2 (page 41), Applicants disclose the SF6 proteins from mouse and human but can also include the SF6 protein from rat, worm, or fish

In addition, the claims are drawn to composition that can be used for the manufacture of an agent to detect or treat metabolic syndrome, metabolic diseases or dysfunctions. The invention is excessively broad because any diseases can be classified as a metabolic syndrome, a metabolic disease or dysfunction. Thus the recitation of claim 14 can include any diseases or syndromes known to Man.

The amount of direction or guidance present

Applicants' disclosure is limited to the characterization of the full length SF6 polypeptide with the genbank accession NP_006150. However, the specification does not provide guidance or direction regarding any structural characteristics for SF6 protein fragments or isoforms. In addition, the specification does not provide any guidance regarding the composition that can be used for the manufacture of an agent to detect or treat metabolic syndrome, metabolic diseases or dysfunctions.

Working Examples

Although Applicant has disclosed that the SF6 protein corresponds to the polypeptide with the genbank accession NP_006150 (page 41, table 2) and examples for the expression of the SF6 mRNA by PCR (example 6), the specification does not provide any examples for a pharmaceutical composition or a kit comprising the SF6 protein corresponding to the polypeptide with the genbank accession NP_006150, a pharmaceutical composition comprising SF6 fragments or isoforms.

In addition, the specification does not provide any methods working examples the manufacture of an agent to detect or treat pancreatic diseases, obesity, metabolic syndrome, metabolic diseases or dysfunctions.

Finally, the specification does not provide any example a fusion protein with a SF6 protein or a kit comprising the SF6 protein.

Please note that the term "preventing" has been interpreted by the Examiner as meaning that an activity will not occur, i.e. diseases will not occur. However, the specification does not provide any example for the manufacture of an agent that prevents a disease from occurring.

The quantity of experimentation needed

It would require undue experimentation for one of skill in the art to be able to use the claimed pharmaceutical composition comprising the SF6 protein fragments or isoforms because the specification and claims have not provided the structural identifying characteristics of the fragments and isoforms of the SF6 protein. In addition, it would require undue experimentation for one skill in the art to use the claimed pharmaceutical composition because Applicants have not provided any identifying characteristics for SF6 protein composition the metabolic syndrome, metabolic diseases or dysfunctions that can be used for the manufacture of an agent to detect or treat metabolic syndrome, metabolic diseases or dysfunctions.

Thus one of skill the art would not be able to use the claimed pharmaceutical composition and kit comprising SF6 protein fragments and isoforms other than Genbank Accession Number NP_006150 because the specification has not provided enough information.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 9, 14, 16, and 18, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuroda et al. (1999, Biochemical and Biophysical Research Communications, Volume 265, pages 79-86).

The claimed invention is drawn to a pharmaceutical composition comprising the protein or function fragment of the protein with the accession number NP_006150 and a kit comprising SF6 amino acid molecule or a function fragment or an isoform thereof. The composition contains pharmaceutically acceptable carriers, diluents, and/or dilutives. The protein in the composition is a recombinant polypeptide. The composition is for application in vitro

Upon further consideration of the claims, the Examiner has taken the position the claimed SF6 protein corresponds to the polypeptide with the genbank accession NP_006150. The protein with the genbank accession NP_006150 corresponds to the protein NELL2 disclosed in the publication by Kuroda et al. (1999).

The reference by Kuroda et al. teaches that NELL2 in present is DMEM medium supplemented with fetal bovine serum (page 80, left column, 5th paragraph) ~~in a dish~~ meeting the limitations of claims 1, 2~~, and 41~~.

In addition, Kuroda et al. teach that NELL2 was recombinantly produced in COS cells from NELL cDNA (page 80, left column, 4th paragraph) meeting the limitation of claim 9.

Moreover, Kuroda et al. teach that NELL2 is used in the in vitro assay immunoprecipitation (page 80, left column, 5th paragraph) meeting the limitations of claim 18.

The teachings of Kuroda et al. would also meet the limitations of claims 14 and 16 because the composition recited in claims 14 and 16 can be used *in vitro*, since the claims do not have any requirement that the agent be used in vivo. The detection of claim 14 and the regeneration of claim 16 can be done *in vitro*.

Please note that claim 15 is not being rejected under 35 USC 102(b) because the reference does not teach a composition for *in vivo* use. However, a product and all of its characteristics are inseparable so

any teaching of the protein of the invention in a pharmaceutical composition would inherently meet the claim limitations regardless of its intended use as recited in these claims.

Finally, the reference by Kuroda et al. meets the limitation of claim 41 because it teaches the recitation of the protein with the genbank accession NP_006150 contained in DMEM (page 80, left column, 5th paragraph) is considered as a kit, in the absence of any other recited elements of the claim.

Conclusion

No claim is allowed.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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November 07, 2008

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